REMARKS/ARGUMENTS

Reconsideration of this Application and entry of this Amendment is respectfully requested.

35 U.S.C. § 103 Rejections

Claims 150-153, 155-163, and 165-170 were rejected under 35 U.S.C. § 103(a) as allegedly being obvious over U.S. Patent No. 5,957,949 to Leonhardt *et al.* (Leonhardt) in view of U.S. Patent No. 6,264,691 to Gabbay (Gabbay). Claims 154 and 164 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Leonhardt in view of U.S. Patent No. 5,104,404 to Wolff (Wolff).[1] Applicants respectfully traverse.

Independent claim 150 recites, among other features, "a valve support . . . configured to be *collapsible for trans luminal delivery* . . . [and] having an axial length sufficient to extend, when implanted, from a position of a native annulus . . . and past the patient's coronary ostia, and into an ascending aorta." The valve support includes "a first section . . . configured to engage the native annulus; and a second section . . . configured to extend past the coronary ostia and into the ascending aorta." Independent claims 160 and 170 recite similar distinguishing features. The Examiner has failed to establish a prima facie case of obviousness for claims 150, 160, and 170 based on the combination of Leonhardt and Gabbay.

The Examiner bears the burden of establishing a prima facie case of obviousness based upon the prior art. *In re Piasecki*, 745 F.2d 1468, 1471-73, 223 U.S.P.Q. 785, 787-88 (Fed. Cir. 1984). "Rejections on obviousness cannot be sustained by merely conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007) (quoting *In re Kahn*, 441 F.3d 977, 988, 78 U.S.P.Q.2d 1329, 1336 (Fed. Cir. 2006)). Obviousness can be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so. *In re Kahn*, 441 F.3d 977, 986 (Fed. Cir. 2006); see also MPEP 2143.01. However, to reject a claim based on this rationale, the Examiner must articulate a finding that there was some reason

[1] Applicants assume that the Examiner intended to reject claims 154 and 164 under 35 U.S.C.§ 103(a) over Leonhardt in view of Gabbay, and in further view of Wolff. Applicants respectfully request confirmation in the next Office Action.

to combine or modify the teachings of the prior art, and a finding that there was a reasonable expectation of success. If any of these findings cannot be made, then this rationale cannot be used to support a conclusion that the claim would have been obvious to one of ordinary skill in the art. *See* "Examination Guidelines for Determining Obviousness under 35 U.S.C. § 103 in view of the Supreme Court decision in *KSR International v. Teleflex Inc.*," Fed. Reg. 72:57526-57535, 57534 (October 10, 2007), hereinafter "Examination Guidelines."

Leonhardt discloses a valve stent 20 that is implanted at the location of the mitral valve, the aortic valve, or in the aorta. (Leonhardt at col. 5, ll. 41-42; col. 9, l.63 to col. 10, l.30; FIGs. 2, 3, and 9D.) Valve stent 20 is radially compressible and deployable via a catheter. (Leonhardt at Abstract.) Valve stent 20 is configured to conform to the tissue immediately around the location of the mitral valve and/or aortic valve, or to bond to the aorta. (Leonhardt at col. 5, ll. 48-52; col. 9, l.63 to col. 10, l.30.) As recognized by the Examiner, "Leonhardt et al. is silent with respect to the length of the stent serving as the valve support." (Office Action at 4.)

The Examiner cites Gabbay for teaching "a heart valve where different stent lengths may be applied to the same heart valve structure." (*Id.*) Gabbay discloses a replacement heart valve device for use during a Ross procedure. (Gabbay at col. 1, ll. 20-33.) During a Ross procedure, the native, diseased aortic valve and a portion of the aorta are excised and replaced with a healthy pulmonic valve. (*Id.*) The device of Gabby includes a cylindrical girdle 10 that is mounted externally of a replacement heart valve disposed within the girdle. (*Id.* at col. 2, ll. 63-65.) The girdle, at its outflow end, is attached to the aorta and, at its inflow end, is attached to the right ventricle outflow tract by sutures. (*Id.* at col. 7, ll. 12-14; col. 7, ll. 30-34; FIGs. 7-9.) Accordingly, the Gabbay girdle and valve replace the excised portion of the aorta and native aortic valve. (*See id.* at FIGs. 7-9.) The Examiner states "[i]t would have been obvious to one having ordinary skill in the art at the time the invention was made to adjust the length of the stent to extend from the annulus into the ascending aorta in order to construct the stent so that it will provide additional support, as needed, to the tissue in the area where the prosthetic valve is being implanted." (*Id.* at 5.) For at least the reasons detailed below, the Examiner has failed to articulate a rational reason why the length of the Leonhardt stent would be modified as taught by Gabbay.

The Examiner asserts that the reason to modify the length of the Leonhard stent is "to construct the stent *so that it will provide additional support, as needed, to the tissue in the area* where the prosthetic valve is being implanted." (Office Action at 5 (emphasis added).) As

discussed above, Leonhardt discloses a radially collapsible valve stent that can be delivered via catheter and subsequently expanded against the native valve structure. In contrast, Gabbay discloses a girdle that encompasses a heart valve that replaces an excised portion of the aorta and the native valve. (Gabbay at col. 1, ll. 20-33; col. 2, ll. 63-65.) Rather than expanding to support and contact the tissue in the area of the prosthetic valve as asserted by the Examiner, the girdle in Gabbay replaces the tissue in the area of the prosthetic valve. Accordingly, one of ordinary skill in the art would have no reason to increase the Leonhardt stent's length in view of a girdle used in a Ross procedure as disclosed in Gabbay. Therefore, the Examiner has failed to establish a prima facie case of obviousness based on the combination of Leonhardt and Gabbay regarding independent claims 150, 160, and 170.

Further, Applicants note that the recited features of independent claims 150, 160, and 170 are more than "a mere change in the size of a component" as asserted by the Examiner. (Office Action at 5.) Claims 150, 160, and 170 recite a particular configuration that has "an axial length sufficient to extend, when implanted, from a position of a native annulus . . . and past the patient's coronary ostia, and into an ascending aorta" as recited in claim 150 and the respective language of claims 160 and 170. Thus, the Examiner necessarily contends that it would have be obvious to extend the length of the Leonhardt mitral valve without any unexpected complications. The Examiner's assertions defy logic. Blockage of the coronary arteries can lead to rapid death of a patient. Dr. Andersen, one of the inventors of the previously asserted patent, discovered this result in his early work with implanted heart valves. (*See* H.R. Andersen *et al.*, *Transluminal Implantation of Artificial Heart Valves. Description of a New Expandable Aortic Valve and Initial Results with Implantation by Catheter Technique in Closed Chest Pigs*, 13 European Heart J. 704, 707 (1992) (noting that the coronary arteries were obstructed in pig no. 3, which only survived 15 minutes after implantation)). Thus, modification of Leonhardt would not involve "mere resizing." To achieve the claimed configurations, which, for example, can reduce the risk that the ostia are occluded, *see, e.g.*, paragraph 142 of the as-filed specification, modifications well beyond a mere resizing of Leonhardt are required.

Thus, Applicants respectfully request that the Examiner reconsider and withdraw the rejection of claims 150, 160, and 170, and claims 151-159 and 161-169, which depend from claims 150 and 160, for at least the foregoing reasons.

Conclusion

For the foregoing reasons, Applicant believes all the pending claims are in condition for allowance and should be passed to issue. The Commissioner is hereby authorized to charge any additional fees which may be required under 37 C.F.R. 1.17, or credit any overpayment, to Deposit Account No. 01-2525. If the Examiner feels that a telephone conference would in any way expedite the prosecution of the application, please do not hesitate to call the undersigned at telephone (707) 543-5484.

Respectfully submitted,

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